

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCI United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|---|----------------|----------------------|-------------------------|-------------------------|--|
| 09/701,933 | 08/20/2001 | Tom Sander | TB-1041A-US | 1292 | |
| 75 | 590 11/22/2004 | | EXAM | INER | |
| Donald J. Pochopien | | | SNOW, BRUC | SNOW, BRUCE EDWARD | |
| MCANDREWS,HELD, & MALLOY, Ltd. 500 West Madison Street Suite 3400 | | | ART UNIT | PAPER NUMBER | |
| | | | 3738 | | |
| Chicago, IL 6 | 0661 | | DATE MAILED: 11/22/2004 | DATE MAILED: 11/22/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | |
|---|--|--|--|--|--|--|
| Office Action Summary | | 09/701,933 | SANDER ET AL. | | | |
| | | Examiner | Art Unit | | | |
| | | Bruce E Snow | 3738 | | | |
| Period fo | The MAILING DATE of this communication app or Reply | pears on the cover sheet with the c | orrespondence address | | | |
| THE - Exte after - If the - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. nsions of time may be available under the provisions of 37 CFR 1.1: SIX (6) MONTHS from the mailing date of this communication. period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tin y within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | and the second s | | | | |
| 1) 又 | Responsive to communication(s) filed on 23 A | uaust 2004. | | | | |
| , | | action is non-final. | | | | |
| 3) | / _ | | | | | |
| Disposit | ion of Claims | | | | | |
| 5)□ 6)⊠ 7)□ | Claim(s) 59-61,65,66 and 69-80 is/are pending 4a) Of the above claim(s) is/are withdraw Claim(s) is/are allowed. Claim(s) 59-61,65,66 and 69-80 is/are rejected Claim(s) is/are objected to. Claim(s) are subject to restriction and/o | wn from consideration. | · | | | |
| Applicati | ion Papers | • | | | | |
| 10) | The specification is objected to by the Examine The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct The oath or declaration is objected to by the Ex | epted or b) objected to by the drawing(s) be held in abeyance. Setion is required if the drawing(s) is ob | e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d). | | | |
| Priority (| under 35 U.S.C. § 119 | | | | | |
| - 12) <u>□</u> a) | Acknowledgment is made of a claim for foreign All b) Some * c) None of: Certified copies of the priority document Certified copies of the priority document Copies of the certified copies of the priority document application from the International Bureau See the attached detailed Office action for a list | s have been received. s have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)). | ion No ed in this National Stage | | | |
| 2) Notice 3) Infor | nt(s) ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other: | | | | |

Priority

Applicant priority is noted. The priority date for applicant's embodiment shown is figures 8A-8c is 8/27/97; the priority date for the embodiment shown in figures 8D-8F is 8/27/98.

Response to Arguments

Applicant's arguments filed 8/23/04 have been fully considered but they are not persuasive. Applicant has amended claim 59 adding the language, "said first side wall and said second side wall being elongated relative to said anterior end and said posterior end." It is the Examiner's position that the implants of both Stroever et al and Pafford et al can be described to meet the language. The labeling of the anterior end and posterior end is arbitrary. Some of the rejections have been changed to reflect the Examiner's position. The implants are fully capable of being inserted between the vertebrae in any direction.

Regarding the Examiner's second interpretation of both rejections, only half of the implant is being used in for the rejection, applicant's use of the transitionary "comprising does not exclude the implant having a second half.

Regarding the combination rejection of Pafford et al and Kuntz, the Examiner's rejection is believed to clear and sensible. Applicant's argument the Pafford et al teaches a hole in the middle does not take away the reasoning for combining. The Examiner notes the election of species in the other applications, however, it is not clear how this influences the current application. Further, it is not clear why an election of species requirement negates a rejection under 35 U.S.C. 103(a).

Application/Control Number: 09/701,933

Art Unit: 3738

The new rejections in view of Coates et al were made to address new claims 78-80.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 59-61, 65-66, 70-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Stroever et al (5,728,159).

Referring to figure 2, Stroever et al teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side

Application/Control Number: 09/701,933

Art Unit: 3738

wall (indicated as P) comprises a concave surface and the first wall (A) comprises a convex surface. The implant is "stretched out" between the anterior end (M) and posterior end (L).

Note that the grooves 18 and 20 produce ridges therebetween which prevent sliding the implant in any direction.

Second interpretation of Stroever et al:

Referring to figure 2, Stroever et al teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall (<u>interior</u> wall of P or M) comprises a concave surface and the first wall (exterior side wall of P or M) comprises a convex surface. The implant is "stretched out" between the anterior end (A) and posterior end (P). Applicant's use of the transitionary "comprising does not exclude the implant having a second half.

Claims 59-61, 65-66, 70-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Pafford (6,371,988).

Referring to all figures specifically figures 25, Pafford teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface (top side in figure 25) and the first wall

Art Unit: 3738

(bottom side in figure 25) comprises a convex surface. The anterior end is on the left side and the posterior end is on the right side.

Page 5

Referring to figure 25, clearly the implant is elongate in one direction.

Claims 59-61, 65-66, 70-80 are rejected under 35 U.S.C. 102(e) as anticipated by Pafford et al (6,371,988) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pafford et al (6,371,988) in view of Kuntz (4,349,921).

Regarding new claim 72, the implants shown in figures 29-42 are free of the intramedullary canal not having the natural shape. Additionally, the rejection under 35 U.S.C. 103(a) making separate halves do not have a through hole.

102 rejection:

Referring to all figures, specifically figures 28-42, Pafford et al teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface and the first wall comprises a convex surface. Note the second side wall is interpreted an interior wall. Applicant's use of the transitionary "comprising does not exclude the implant having a second half.

103 rejection:

Applicant is claiming the implant taught by Pafford et al, shown in figures 29-32, however is claiming only half of the implant. Kuntz teaches a spinal implant can be

formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6. It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Pafford et al because "when a prosthesis for the lumber area is required, it has been found advantages to make the prosthesis in two halves.." see column 9, lines 41 et seq.

Also see MPEP2144.04, C. Making Separable.

Claims 59-61, 65-66, 70-80 are rejected under 35 U.S.C. 102(e) as anticipated by Coates et al (5,989,289) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Coates et al (5,989,289) in view of Kuntz (4,349,921).

Regarding new claim 72, the implants shown in figures 29-42 are free of the intramedullary canal not having the natural shape. Additionally, the rejection under 35 U.S.C. 103(a) making separate halves do not have a through hole.

Note at least figure 19 teaching ridges identical to applicant's.

102 rejection:

Referring to all figures, Coates et al teaches a bone implant comprising a substantially planar upper and lower surfaces, an anterior end and a posterior end, a first side wall and second side wall opposite said first side wall, wherein the first and second side walls extend between the planar surfaces, and wherein the second side wall comprises a concave surface and the first wall comprises a convex surface. **Note**

the second side wall is interpreted an interior wall. Applicant's use of the transitionary "comprising does not exclude the implant having a second half.

103 rejection:

Applicant is claiming the implant taught by Coates, however, is claiming only half of the implant. Kuntz teaches a spinal implant can be formed in a singular configuration, as shown in figures 1-4, or in two halves, as shown in figures 5-6. It would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Coates et al because "when a prosthesis for the lumber area is required, it has been found advantages to make the prosthesis in two halves.." see column 9, lines 41 et seq.

Also see MPEP2144.04, C. Making Separable.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3738

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

BRUCE SNOW
PRIMARY EXAMINER